

Remplir™

DESCRIPTION

Remplir™ is a sterile, resorbable collagen membrane intended for use in peripheral nerve repair.

Remplir™ is a highly purified collagen membrane of porcine origin produced using quality-controlled manufacturing processes. Raw materials are sourced exclusively from within Australia and collected at certified facilities under strict quality controls. The collagen is purified to remove materials that may elicit antigenic reactions. Remplir™ is manufactured without crosslinking.

PROPERTIES

Remplir™ is designed to protect the injured nerve following repair and provide a favourable environment for nerve regeneration to occur. Remplir™ collagen membranes permit passage of fluids but act as a barrier to cellular ingrowth.

Remplir™ is soft and pliable with excellent handling characteristics. Remplir™ is wettable and may be sutured in place, if required. Animal studies have shown that Remplir™ is still visible 5-13 weeks after implantation but is fully resorbed through normal physiological processes within 26 weeks.

INDICATIONS FOR USE

Remplir™ is indicated for the repair of peripheral nerve injuries.

DIRECTIONS FOR USE

These directions are intended as a general guide and are not intended to supersede professional clinical judgement.

1. Follow standard procedures for nerve exposure and mobilisation. Perform neurolysis and/or coaptation of nerve ends if required.
2. Hydrate Remplir™ with sterile saline or other physiological solution.
3. Trim Remplir™ to size and wrap around the site of nerve injury/repair without constricting or compressing the nerve.
4. If necessary, fix Remplir™ in place with atraumatic sutures.
5. Follow standard post-operative procedures and care. Application of Remplir™ does not modify post-operative treatment.

LIMITATIONS OF USE

Contraindications

The use of Remplir™ in patients with known sensitivity to porcine-derived materials or collagen is contraindicated.

Adverse reactions

Possible complications of peripheral nerve surgery include pain, infection, swelling, inflammation, foreign body sensation and changes in nerve sensitivity (paraesthesia or hyperaesthesia) at the implant site.

Adverse reactions to porcine-derived collagen membranes such as Remplir™ are extremely rare. Patients should be monitored closely in the initial post-operative period to identify and address any adverse reactions that may occur.

Precautions

Safety and efficacy for use in patients <18 years cannot be assured.

Peripheral nerve repair with Remplir™ should only be undertaken by suitably qualified surgeons.

SYMBOLS USED IN LABELLING



Use-by date



Batch code



Catalogue number



Distributor



Sterilized using irradiation



Do not re-sterilize



Do not use if package is damaged



Double sterile barrier system



Keep away from sunlight



Keep dry



Temperature limit



Do not re-use



Consult instructions for use

STORAGE AND HANDLING

Store Remplir™ in its original packaging at room temperature (15-25°C) in a dry place

HOW SUPPLIED

Remplir™ is supplied in a double PETG/Tyvek blister pack contained in a labelled cardboard box.

Cat. No.	Size
ON-152	Remplir™ 15 x 20 mm
ON-203	Remplir™ 20 x 30 mm
ON-304	Remplir™ 30 x 40 mm
ON-405	Remplir™ 40 x 50 mm



Manufacturer

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If you have any concerns or questions about this product, please contact Orthocell.

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